Researchers develop low-cost medical ventilators for global disasters

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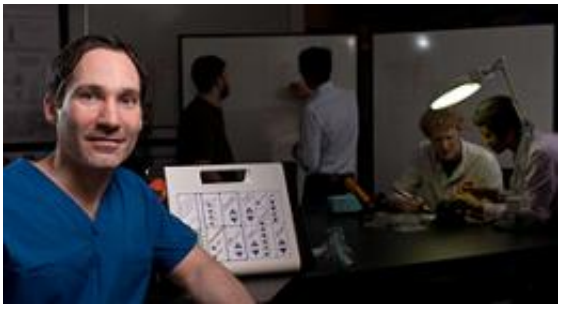

After learning that his hospital would be short ventilators in the event of an influenza pandemic, Matthew Callaghan sketched out concepts for a less inexpensive ventilator on a napkin at a lunchtime meeting with a fellow physician. Credit: Steve Fisch

(PhysOrg.com) -- Matthew Callaghan, MD, had an epiphany about medical device design during a pandemic planning meeting, when his hospital was drafting a worst-case scenario protocol to decide which types of patients would receive life support from the hospital's limited number of breathing ventilators.

"The physicians assumed that we'd have to ration the ventilators, and that if we put the criteria on paper, we wouldn't feel bad about the life-or-death decisions we were making," said Callaghan. "All of a sudden, I realized that the task force wasn't addressing the root problem. So I asked, 'Why not design a cheaper ventilator so rationing isn't

necessary?”

So Callaghan started to think about why ventilators, which primarily move air in and out of impaired lungs, cost upwards of $40,000, and why no one had designed a low-end model that could be stockpiled for large-scale disasters.

Fortunately, the fact that he was a surgical resident at UC-San Francisco at the time wasn’t a mental barrier for Callaghan, who has degrees in product design and biology from Carnegie Mellon, a medical degree from State University of New York, a medical fellowship from New York University and now a postdoctoral position in Stanford University’s biodesign program. In addition, his kindergarten report card probably said, “He colors outside of the lines.”

He began by inviting a physician friend to lunch, and they began sketching some ideas on a napkin. After learning that the United States would be short about 700,000 ventilators during a moderate-to-severe influenza pandemic, they realized that they might be able to build a business around their ideas.

Three years later, Callaghan’s team is close to commercially launching a low-cost ventilator, called OneBreath, which will be the first device specifically designed to address the global shortage of emergency The OneBreath ventilator went from napkin sketch to finished product with the help of Stanford Biodesign, a training incubator in medical technology that brings together multidisciplinary teams of medical, engineering, law and business school students to address unmet medical needs with innovative approaches. This program, which was founded 10 years ago, has jump-started a number of successful innovations, including a new approach to minimally invasive spine surgery (Simpirica Spine); a more cost-effective way to diagnose heart rhythm abnormalities (iRhythm); and a device to accelerate healing of skin

ulcers (Spiracur). Stanford Biodesign recently established joint programs in India and Singapore to specifically help accelerate medical solutions for underserved populations.

The Stanford Biodesign credo is that medical innovation can be taught, and all design teams learn a systematic approach to needs finding, invention and implementation. Before biodesign fellows even get close to building a prototype, they spend three months on clinical observation, asking questions, identifying needs, analyzing markets and brainstorming concepts. Along the way, they also learn about managing intellectual property, the regulatory process and medical reimbursements, applying this knowledge to their specific projects.

“We say that a well-characterized need is the DNA of a good invention. It’s a lot of work to get the need right, but once you are there, the invention will almost certainly follow,” said Paul Yock, MD, director of Stanford Biodesign.

With the help of this methodology, members of Callaghan’s team were able to focus their concepts to more effectively address a need device manufacturers missed — the pandemic/disaster ventilator market in developing nations. In these areas of explosive population growth, health-care infrastructure is limited, and the demand for low-cost ventilators is great, especially in China, where large influenza outbreaks are common.

“Our team decided to design a ventilator that could operate in the middle of nowhere during emergencies, without all the bells and whistles — such as remote monitoring or neonatal care — that are not only hard to use, but are only needed for one in 1,000 patients,” said Callaghan.

By starting with a narrow design target, the form and function of their device began to diverge radically from hospital ventilators, which often resemble 747 cockpits on rollers, with busy computer screens, control

modules, air reservoirs, oxygen supplies and a tangle of cords and tubes.

Structurally, the OneBreath team lowered manufacturing costs by reducing the number of parts; airflow is measured and controlled with propriety software rather than hardware. To ensure operability and portability during earthquakes, floods, tsunamis and other disasters, the compact plastic housing is rugged, grime-resistant, stackable and easy to carry. To cope with power outages, units come with a seven-hour rechargeable battery. Because expert technicians are few and far between during disasters, the units are simple enough for novices to operate and repair, and breathing tube replacement costs are 50 cents, rather than the $180 required with high-end ventilators.

With an out-the-door cost targeted at less than $800, OneBreath's retail price should be a fraction of comparable ventilators, priced so that governments and institutions can afford to stockpile units for potential disasters.

Thomas Krummel, MD, chair of the Department of Surgery and a Stanford Biodesign co-director, is enthusiastic about the project: "I love the duality of the OneBreath solution, the way its affordability addresses the West's need for pandemic preparedness, while at the same time addressing the developing world's need for basic, inexpensive ventilators." So far the product has been well-received; it was named a Popular Science Invention of the Year in 2010 and has won awards from the American Association for Respiratory Care, the American College of Surgery Clinical Congress and NCIAA BMEidea.

Callaghan credits the Stanford entrepreneurial spirit, in part, for OneBreath's success.

"When we needed a business plan, we visited the Stanford Graduate School of Business, and three students wrote our plan as part of a class

assignment. After we built our first cardboard prototypes, we went over to Stanford's pulmonary and critical care office with donuts and coffee, and the physicians were happy to provide user feedback."

Before his biodesign fellowship, Callaghan had no idea how hard it was to get a medical device through the regulatory process: "I laugh when I look back at our early grant applications, where we estimated that it'd take $20,000 and seven months to get our device approved by the FDA."

Thus far, the biodesign-led development process has taken two years, with the addition of a Wallace H. Coulter Foundation grant and award money from a number of design competitions. Biodesign is supported from a variety of internal and external sources, including pilot and fellowship grants from Spectrum, the organization that oversees Stanford's NIH-funded Clinical and Translational Science Award. Callaghan estimates it'll take at least another year and $2.5 million to usher OneBreath through final testing, agency approvals, pilot manufacturing and lockdown of technical documentation. If the device is successfully launched, all the intellectual property holders — the OneBreath inventors, the investors and Stanford — share in any future profits.

While they're waiting for agency approvals in the United States and Europe, they'll field test pilot units in China and India. By documenting their successes overseas, they hope to convince U.S. institutional buyers, who often perceive lower-priced medical devices as less effective or risky, to give their ventilators a try.

Callaghan is now going through the bittersweet process of transitioning his recently incorporated company to a new CEO, Bryan Loomas, who has 27 years in the medical device business; and a VP of business development, Frederick Winston, who graduated from the Stanford Graduate School of Business. Stephen Ruoss, MD, associate professor of

pulmonary and critical care medicine is Callaghan's technical advisor.

Looking forward, Callaghan has several new medical ideas that he's eager to develop. His advice to others with similar aspirations: "Assemble a small team of quality people — engineers, physicians, MBAs — who are all willing to wear multiple hats. In a start-up, everyone needs to do everything, from spell-checking brochures to taking out the trash."

Provided by Stanford University Medical Center